titioner's Docket No.

2960/116

Application No.: 10/724,010 Supplemental Information Disclosure Statement

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Berez et al.

Application No.: 10/724,010

Filed: November 25, 2003

Examiner: Philogene, Pedro

Group No.: 3732

For: Patient Selectable Joint Arthroplasty Devices and Surgical Tools Facilitating Increased

Accuracy, Speed and Simplicity in Performing Total and Partial Joint Arthroplasty

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BEFORE MAILING DATE OF EITHER A FINAL ACTION OR NOTICE OF ALLOWANCE (37 C.F.R. § 1.97(c))

TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

- 1. The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but before the mailing date of either
 - (1) a final action under § 1.113 or
 - (2) a notice of allowance under § 1.311

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37 C.F.R. § 1.10*

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Alexander J. Solenski, Jr., Esq. (type or print name of person certifying)

^{*} Only the date of filing (\$1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§.1.10) or facsimile transmission (§.1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

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FEE

2. Accompanying this transmittal is the fee for submission of an information disclosure statement under section 1.97(c). (\$180.00)

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3. Applicant elects the option to pay the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c) (\$180.00).

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Charge any additional fees required by this paper or credit to deposit account No. 19-4972.

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DATE: May 31, 2005

Alexander J. Smolenski, Jr., Esq. BROMBERG & SUNSTEIN LLP

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125 Summer Street

Boston, MA 02110-1618

US

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Practitioner's Docket No.	20/0/44/		
'ractitioner's Docket No	2960/116		

Practitioner's Docket No. 2960	/116	PATENT
IN THE UNITED S	TATES PATEN	T AND TRADEMARK OFFICE
Patent application		
of		
	Invento	or(s)
for		
	Title of in	vention
the specification of which is being tran	nsmitted herewith	OR
In re application of: Berez et al.		
Application No.: 10/724,010	Group No.:	3732
Filed: November 25, 2003	Examiner:	Philogene, Pedro
		vices and Surgical Tools Facilitating Increaseding Total and Partial Joint Arthroplasty
P.O. Box 1450		
Alexandria, VA 22313-1450		
	INFORMATIO	ON DISCLOSURE STATEMENT
		(Information Disclosure Statementpage 1of 15)
		7.R. SECTIONS 1.8(a) and 1.10*
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	Express Mail certific	ation is optional.)
I hereby certify that, on the date shown below	, this correspondence	e is being:
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[x] deposited with the United States Postal Service 22313-1450	in an envelope addres	sed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA
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Date: May 31, 2005

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).
- NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).
- NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Supplemental Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

- 1. [x]Preliminary Statements
- 2. [x]Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
- 3. []Statement as to Information Not Found in Patents or Publications
- 4. []Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
- 5. []Cumulative Patents or Publications
- 6. [x]Copies of Listed Information Items Accompanying This Statement
- 7. []Concise Explanation of Non-English Language Listed Information Items
 - 7A. []EPO Search Report
 - 7B. [x]English Language Version of EPO Search Report
- 8. []Translation(s) of Non-English Language Documents
- 9. []Concise Explanation of English Language Listed Information Items (Optional)
- 10. [x]Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate), respectively, have been continued on ADDED PAGE(S).

Sections

(Information Disclosure Statement--page 2 of 13)

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Berez et al.

Attorney Docket:

2960/116

Serial No:

10/724,010

Art Group Unit:

3732

Date Filed:

November 25, 2003

Examiner Name:

Philogene, Pedro

Invention:

Patient Selectable Joint Arthroplasty Devices and Surgical Tools

Facilitating Increased Accuracy, Speed and Simplicity in Performing Total

and Partial Joint Arthroplasty

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

	U.S. PATENT DOCUMENTS								
Examiner	Reference	Document	Issue Date/	Inventor	Class/Subclass				
Initials	Number	Number	Publication Date						
	AA	US 5,344,459	Sep. 1994	Swartz	623/18				
	AB	US 5,827,289	Oct. 1998	Reiley et al.	606/86				
	AC	US 6,328,765	Dec. 2001	Hardwick et al.	623/23.72				
	AD	US 6,352,558	Mar. 2002	Spector, M.	623/18.11				
	AE	US 6,358,253	Mar. 2002	Torrie et al.	606/96				
	AF	US 6,375,658	Apr. 2002	Hangody et al.	623/20.18				
	AG	US 6,443,988	Sep. 2002	Felt et al.	623/17.12				
	AH	US 6,520,964	Feb. 2003	Tallarida et al.	606/71				
	AI	US 6,632,235	Oct. 2003	Weikel et al.	606/192				
	AJ	US 6,652,587	Nov. 2003	Felt et al.	623/20.16				
	AK	US 6,679,917	Jan. 2004	Ek S. W.	623/20.14				

U.S. PATENT DOCUMENTS							
Examiner Reference Document Issue Date/ Inventor Class/Subclass							
Initials	Initials Number Publication Date						
	AL	US 2002/0059049	May 2002	Bradbury et al.	703/111		

		F(OREIGN PATE	NT DOCUMENT	rs		
Examiner	Reference	Country	Document	Publication	Patenteee or	Class/Subclass	
Initials	Number	Code	Number	Date	Applicant		
	AM	WO 93/25157		Dec. 1993	Rau et al.	A61B 17/56	
	AN	WO	01/19254	Mar. 2001	Cummings et	A61B 17/00	
					al.		
	AO	WO	01/91672	Dec. 2001	Hanke, G.	A61F 2/36	
	AP	WO	02/34310	May 2002	Dickson et al.	A61L 31/04	
	AQ	WO	02/23483	Mar. 2002	Steines et al.	G06T 11/0	
	AR	wo	04/043305	May 2004	Tsougarakis	A61F 2/30	
i					et al.		
	AS	EP	0 626 156	Jan. 1992	Walker, P.S.	A61F 2/38	

		OTHER DO	OCUMENTS				
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date				
	AT .	Taha et al.	"Modeling and design of a custom made cranium implant for large skull reconstruction before a tumor removal", Phidias Newsletter No. 6, pages 3-7, June 2001. Retrieved from the Internet: URL:http://www.materialise.com/medical/files/pdf				
	AU	Kidder et al.	"3D model acquisition, design, planning and manufacturing of orthopaedic devices: a framework", Proceedings of the SPIE – Advanced Sensor and Control-System Interface, Boston, MA, Vol. 2911, pgs. 9-22, 21 November 1996				
	AV	Carr J.C. et al.	"Surface Interpolation with Radial Basis Functions for Medical Imaging", IEEE Transactions on Medical Imaging, IEEE, Inc., New York, Vol. 16, No. 1, 1 February 1997, pgs. 96-107				
	AW	C.S. Ranawat et al.	"MacIntosh Hemiarthroplasty in Rheumatoid Knee" Acta Orthop Belg. 1973 Jan-Feb: 39(1):102-112				

OTHER DOCUMENTS (cont.)

		OTHER DOCUME	
	AX	B. Blum et al.	"Knee Arthroplasty in Patients with
			Rheumatoid Arthritis", Ann. Rheum. Dis.
			1974 Jan: 33(1):1-11
	AY	Nelson M.D. et al.	"Arthroplasty and Arthrodesis of the Knee
			Joint", Orthop. Clin. North Am. 1971 Mar:
	İ		2(1):245-264
	AZ	McCollum et al.	"Tibial Plateau Prosthesis in Arthroplasty of
			the Knee", J. Bone Joint Surg. Am. 1970
			Jun:52(4):827-828
	BA	Hastings D.E. et al.	"Double Hemiarthroplasty of the Knee in
			Rheumatoid Arthritis. A Survey of Fifty
	•		Consecutive Cases", J. Bone Joint Surg. Br.
			1973 Feb:55(1): pgs. 112-118
	BB	Schron, D. et al.	"MacIntosh Arthroplasty in Rheumatoid
		,	Arthritis", Rheumatol Rehabil. 1978
			Aug:17(3): pgs. 155-163
	BC	McKeever, D. C. et al.	"The Classic Tibial Plateau Prosthesis", Clin
1			Orthop. Relat. Res. 1985 Jan-Feb. (192):3-12
	BD	Conaty et al.	"Surgery of the Hip and Knee in Patients
			with Rheumatoid Arthritis", J. Bone Joint
			Surg. Am. 1973 Mar:55(2): pgs. 301-314
	BE	MacIntosh D. L. et al	"The Use of the Hemiarthroplasty Prosthesis
		17401110511 51 21 01 11	for Advanced Osteoarthrisis and
			Rheumatoid Arthritis of the Knee", J. of
			Bone & Joint Surg. 1972, Vol. 54B. No. 2,
			pgs. 244-255
	BF	MacIntosh D.L.	"Arthroplasty of the Knee in Rheumatoid
1			Arthritis Using the Hemiarthroplasty
1			Prosthesis:, Synovectomy and Arthroplasty
			in Rheumatoid Arthritis, pp. 79-80, Second
1			Int'l. Symposium, Jan. 27-29, 1967 (Basle,
			Switzerland)
	BG	MacIntosh, D.L.	"Hemiarthroplasty of the Knee Using a
	20	Translituosii, Evili	Space Occupying Prosthesis for Painful
			Varus and Valgus Deformities", J. Bone
		·	Joint Surg. Am. 1958 Dec:40-A: pg. 1431
	BH	Stauffer R. et al.	"The MacIntosh Prosthesis. Prospective
		Summit and the	Clinical and Gait Evaluation", Arch. Surg.
			1975 Jun:110(6) pgs. 717-720
	BI	Clary B. B. et al.	"Experience with the Use of the MacIntosh
			Knee Prosthesis", South Med. J. 1972
			Mar:65(3) pgs. 265-272
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OTHER DOCUMENTS (CONT.)

		OTHER DOCUME	
	BJ	Ghelman M.D. et al.	"Kinematics of the Knee After Prosthetic Replacements", Clin. Orthop. 1975 May:
			(108): pgs. 149-151
	BK	Henderson, M.D. et al.	"Experience with the Use of the MacIntosh
	DK.	Henderson, M.D. et al.	Prosthesis in Knees of Patients with
			Rheumatoid Arthritis", South. Med. J. 1969
			·
	BL	Potter M.D.	Nov: 62(11) pgs. 1311-1315 "Arthroplasty of the Knee with Tibial
	BL	Potter WLD.	, <u> </u>
			Metallic Implants of the McKeever and
			MacIntosh Design", Sug. Clin. North Am.
		The state of the s	1969 Aug: 49(4) pgs. 903-915
	BM	Potter T.A., et al.	"Arthroplasty of the Knee in Rheumatoid
			Arthritis and Osteoarthritis: A Follow-up
			Study After Implantation of the McKeever
			and MacIntosh Prostheses", J. Bone Joint
			Sug. Am. 1972 Jan: 54 (1) pgs. 1-24
	BN	Bogoch, M.D. et al.	"Supracondylar Fractures of the Femur
			Adjacent to Resurfacing and MacIntosh
			Arthroplasties of the Knee in Patients with
			Rheumatoid Arthritis", Clin. Orthop. 1988
			Apr. (229): pgs. 213-220
	BO	Cameron et al.	"Review of a Failed Knee Replacement and
			Some Observations on the Design of a Knee
			Resurfacing Prosthesis", Arch. Orthop
			Trauma Surg. 1980: 97(2); pgs. 87-89
	BP	Kates, A. et al.	"Experiences of Arthroplasty of the
			Rheumatoid Knee Using MacIntosh
			Prostheses", Ann. Rheum. Dis. 1969 May:
			28(3) pg. 328
	BQ	Jessop, J.D. et al.	"Follow-up of the MacIntosh Arthroplasty of
		_	the Knee Joint", Rheumatol Phys. Med. 1972
			Feb: 11(5) pgs. 217-224
	BR	Andersson, G.B. et al.	"MacIntosh Arthroplasty in Rheumatoid
			Arthritis", Acta. Orthrop. Scand. 1974: 45
	-		(2) pgs. 245-259
	BS	Wordsworth, et al.	"MacIntosh Arthroplasty for the
		,	Rheumatoid Knee: A 10-year follow up",
			Ann. Rheum. Dis. 1985 Nov. 44(11) pgs. 738-
			741
	BT	Kay, N.R. et al.	"The MacIntosh Tibial Plateau
		, ,	Hemiprosthesis for the Rheumatoid Knee",
			J. Bone Joint Surg., 1972 May, Vol. 54, No. 2,
			pgs. 256-262
L			T KPn. 400-404

OTHER DOCUMENTS (cont.)

BU	Porter, M. L. et al.	"MacIntosh Arthroplasty: a long-term		
		review", J.R. Coll. Surg. Edinb. 1988 Jan-		
		Feb: (192); pgs. 199-201.		
BW		International Search Report dated 23		
		February 2005.		
BV		International Search Report dated 28 March		
		2005.		

Examiner Signature:
Date Considered:
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include:

"A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed;
and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included..."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

[x]Exception(s)	to	above:
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[]Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

[]Cumulative patents or publications identified in Section 5.

U.S. patent citations are not included pursuant to the United State Patent and Trademarks Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.

Section 7A. Concise Explanation of Non-English Language Listed Information Items—EPO Search Report

The relev	ance with respect to	the followi	ng citations	s listed of	on Forms	PTO/SB/08A	and 08B	(substitute
for PTO-1449	9):							

is submitted on the basis of the accompanying:

(check the appropriate item)

[X]EPO search report that is in the English language,

[]EPO search report that is not in the English language and that is accompanied also by an English language version of the EPO search report,

that issued on the corresponding European patent application.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is	•
(check ed	ach applicable item)
(a) []the inventor(s) who signs below	
	SIGNATURE OF INVENTOR
	(type name of inventor who is signing)
(b) []an individual associated with the fill 1.56(c))	ling and prosecution of this application (37 C.F.R. section
	SIGNATURE OF INVENTOR
	(type name of inventor who is signing)
(c) [x] the practitioner who signs below or	n the basis of the information:
(check ea	ach applicable item)
[] supplied by the inventor(s	s).
7.7	dual associated with the filing and prosecution of this C.F.R. section 1.56(c)).
[x] in the practitioner's file.	

Application No. 10/724,010
Supplemental Information Disclosure Statement

SIGNATURE OF PRACTITIONER

Alexander J. Smolenski, Jr., Esq.
(type or print name of practitioner)

125 Summer Street, 11th Floor
P.O. Address

Boston, MA 02110

Reg. No.: 47,953

Tel. No.: (617) 443-9292

Customer No.: 002101

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